SEP 16 2004

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510(k) SUMMARY

A. Submitter Information:

Submitter:	MEDCOMP® 1499 Delp Drive Harleysville, PA 19438 (215) 256-4201 Telephone (215) 256-9191 Fax
Contact:	Jean Callow Regulatory Specialist
Date Prepared:	April 27, 2004

B. Trade Name: Medcomp® T-3
Common Name: Hemodialysis, Apheresis and Infusion Catheter, Non-implanted
Classification: NIE
C.F.R. Section: 876.5540

C. Predicate Devices: K020089 Mahurkar® Triple Lumen Catheter
K973561 Medcomp® Tri-Flow™ Triple Lumen Catheter

D. Device Description:

The Medcomp® T-3 catheter is a 15.5 polyurethane, triple lumen catheter used to remove and return blood with a third internal lumen for infusion. The Medcomp® T-3 catheter is comprised of a soft thermosensitive, radiopaque polyurethane material that is rigid upon insertion and once it reaches body temperature becomes soft to reduce vessel trauma. The lumens are connected to the extensions via a soft pliable hub with a suture wing for secure placement. Clamps are provided on the extension tubes to prevent air/fluid communication. The luers and clamps are color coded, red for arterial, blue for venous and a clear luer for infusion of drugs, TPN or fluid administration.

The catheters are available in 15.5F. The catheter is offered in 28 and 32cm.

The Medcomp® T-3 catheter is packaged with the necessary accessories to facilitate catheter insertion.

E. Intended Use:

The Medcomp® T-3 catheter with a third internal lumen for infusion is indicated for use in attaining short-term vascular access for hemodialysis

and apheresis. The third lumen allows infusion of fluids, medications, and/or when nutritional therapy is prescribed.

This catheter may be inserted via the subclavian vein.

F. Comparison to Predicate Devices:

The Medcomp® T-3 catheter is substantially equivalent to the predicate devices in terms of its intended use, insertion method, anatomical location, design, material type, performance and method of sterilization.

G. Performance Data:

In-vitro performance data for the Medcomp® T-3 catheter including force at break, air and liquid leakage, recirculation, and flow performance demonstrate that this device is substantially equivalent to the legally marketed predicate devices. In vitro testing was performed on the Medcomp® T-3 catheter to assure reliable design and performance in accordance with ISO 10555-1 and 10555-3.

Clinical safety and effectiveness is addressed in 510(K)020089.

Biocompatibility testing on the Medcomp® T-3 catheter demonstrates that the materials used meet the requirements of ISO 10993 for a permanent contact device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 16 2004

Ms. Jean Callow
Regulatory Specialist
MEDCOMP®
1499 Delp Drive
HARLEYSVILLE PA 19438

Re: K033570
Trade/Device Name: Medcomp® T-3
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: II
Product Code: 78 NIE
Dated: August 25, 2004
Received: September 7, 2004

Dear Ms. Callow:

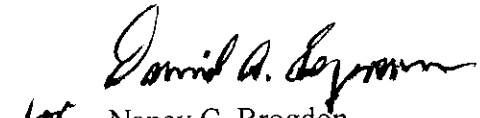
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note:* If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration (21 CFR Part 807); listing (21 CFR Part 807), labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market. If you desire specific advice for your device on the labeling regulation, please contact the Office of Compliance at (301) 594-4616. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K033570

Device Name: MEDCOMP® T-3

Indications for use:

THE MEDCOMP® T-3 CATHETER IS INDICATED FOR USE IN ATTAINING SHORT-TERM VASCULAR ACCESS FOR HEMODIALYSIS, APHERESIS AND INFUSION.

IT MAY BE INSERTED PERCUTANEOUSLY AND IS PRIMARILY PLACED IN THE INTERNAL JUGULAR VEIN OF AN ADULT PATIENT. ALTERNATE INSERTION SITES INCLUDE THE SUBCLAVIAN VEIN.

THE MEDCOMP® T-3 CATHETER IS INDICATED FOR A DURATION LESS THAN (30) DAYS.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter _____
(Per 21 CFR 801.109)

David R. Seymour
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K033570

(Optional Format 1-2-96)